

IN THE CLAIMS:

1. **(Currently amended)** A botanical drug or dietary supplement, for the treatment of or for use in patients with Hepatitis C infection, ~~comprising botanical raw materials, botanical drug substances or botanical ingredients~~ consisting essentially of extracts from ~~each of~~ the following plant species sources:

- (a) ~~The~~ the fruit of Silybum marianum;
- (b) ~~The~~ the root of Astragalus membranaceus var mongholicus or Hedysarum polybotrys;
- (c) ~~The~~ the root of Salvia miltiorrhiza, Salvia bowleyana or Salvia przewalskii; and
- (d) ~~The~~ the fruit of Schisandra chinensis or Schisandra sphenanthera.

2. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 1 wherein each species is present in an amount, relative to the total weight of all ~~of the botanical raw materials, botanical drug substances or botanical ingredients~~ extracts, as follows:

- (a) Silybum ~~spp.~~ from 22-48%;
- (b) Astragalus ~~spp.~~ or Hedysarum ~~spp.~~ from 20-63%;
- (c) Salvia ~~spp.~~ from 13-48%; and
- (d) Schisandra ~~spp.~~ from 2-19%.

3. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 2 wherein each ~~species extract~~ is present in an amount by weight percent as follows:

- (a) Silybum ~~spp.~~ from 30-40%;
- (b) Astragalus or Hedysarum ~~spp.~~ from 20-30%;
- (c) Salvia ~~spp.~~ from 20-30%; and
- (d) Schisandra ~~spp.~~ from 7.5-15%.

4. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 3 wherein each ~~species extract~~ is present in an amount by weight percent as follows:

- (a) Silybum ~~spp.~~ about 35%;
- (b) Astragalus or Hedysarum ~~spp.~~ about 26%;
- (c) Salvia ~~spp.~~ about 26%; and
- (d) Schisandra ~~spp.~~ about 11%.

5. **(Cancelled)**

6. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[5]] ~~1~~ further ~~comprising~~ including excipients.

7. **(Cancelled)**

8. **(Cancelled)**

9. **(Cancelled)**

10. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] ~~1~~ wherein the ~~botanical drug substance~~ extract from the ~~Silybum spp.~~ is ~~standardised~~ standardized against a marker of silybin.

11. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] ~~1~~ wherein the ~~botanical drug substance~~ extract from the ~~Silybum spp.~~ comprises at least 30% by weight silybin and isosilybin when calculated using HPLC.

12. **(Currently amended)** A botanical drug or dietary supplement as claimed in ~~any of~~ claim [[9]] ~~10~~ wherein the ~~standardised~~ standardized extract of the ~~Silybum spp.~~ is a brownish yellow powder which ~~is or~~ has:

- (i) no less than 30% silybin by HPLC;
- (ii) no more than 0.5% soluble in pentane;
- (iii) a sulphated ash content of no more than 1% by weight;
- (iv) a heavy metal content of no more than 100ppm;
- (v) a residual organic solvent content of no more than 1% ethanol, no more than 0.01% ethyl acetate and no more than 0.01% hexane by weight;
- (vi) a bacterial content of no more than 1000 cfu/g; and
- (vii) a fungal content of no more than 100cfu/g.

13. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] ~~1~~ wherein the ~~botanical drug substance~~ extract from the ~~Astragalus spp.~~ is standardised against a marker of Astragaloside IV.

14. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 13 wherein the ~~botanical drug substance~~ extract from ~~the Astragalus spp.~~ comprises at least 0.4% by weight Astragaloside IV when calculated using HPLC.

15. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 13 wherein the ~~botanical drug substance~~ extract from ~~the Astragalus spp.~~ has a TLC chromatographic fingerprint substantially as illustrated in Fig 1 or a HPLC fingerprint substantially as illustrated in Fig 4.

16. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 13 wherein the ~~standardised~~ standardized extract of ~~Astragalus spp.~~ is a pale yellow powder which ~~is or~~ has:

- (i) no less than 0.4% Astragaloside IV by weight;
- (ii) a total ash content of no more than 5% by weight;
- (iii) an acid insoluble ash content of no more than 2% by weight; and
- (iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.

17. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein the ~~botanical drug substance~~ extract from ~~the Salvia spp.~~ is standardised against a marker of Tanshinone II A.

18. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 17 wherein the ~~botanical drug substance~~ extract from ~~the Salvia spp.~~ comprises at least 1.5% by weight of Tanshinone IIA as calculated using HPLC.

19. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 17 wherein the ~~botanical drug substance~~ extract from ~~the Salvia spp.~~ has a TLC chromatographic fingerprint substantially as illustrated in Fig 2 or a HPLC fingerprint substantially as illustrated in Fig 6.

20. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 17 wherein the ~~standardised~~ standardized extract of ~~the Salvia spp.~~ is a dark red powder which ~~is or~~ has:

- (i) no less than 1.5% by weight Tanshinone IIA by HPLC;
- (ii) a total ash content of no more than 5% by weight;
- (iii) an acid insoluble ash content of no more than 2% by weight; and
- (iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.

21. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein ~~botanical drug substance~~ the extract from ~~the Schisandra spp.~~ is ~~standardised~~ standardized against a marker of Schizandrol A.

22. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 21 wherein the ~~botanical drug substance~~ extract from ~~the Schisandra spp.~~ comprises at least 2.0% by weight Schizandrol A using HPLC.

23. **(Currently amended)** A botanical drug ~~substance, or dietary supplement~~ as claimed in claim 21 wherein the ~~botanical drug substance~~ extract from ~~the Schisandra spp.~~ has a TLC chromatographic fingerprint substantially as illustrated in Fig 3 or a HPLC fingerprint substantially as illustrated in Fig 8.

24. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 22 wherein the ~~standardised~~ standardized extract of ~~Schisandra spp.~~ is a brownish red powder which ~~is or~~ has:

- (i) no less than 2.0 % by weight Schizandrol A;
- (ii) a total ash content of no more than 5% by weight;
- (iii) an acid insoluble ash content of no more than 2% by weight; and
- (iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.

25. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 wherein ~~the standardised~~ each extract is a dried ethanolic extract.

26. **(Cancelled)**

27. **(Cancelled)**

28. **(Cancelled)**

29. **(Cancelled)**

30. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 which is provided in a unit dosage form.

31. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 ~~which is~~ wherein the extracts are a suspension powder mixture.

32. **(Currently amended)** A botanical drug or dietary supplement as claimed in ~~claims 31~~ claim 1 further ~~comprising~~ including as excipients:

(a) at least one ~~or more~~ gellants ~~gellant~~ or thickeners ~~thickener~~ comprising at least one xanthum gum having a particle size distribution such that 100% by weight of the particles pass a 60 mesh sieve, 95% by weight of the particles pass a 80 mesh sieve and 70% by weight of the particles pass a 200 mesh sieve,

(b) at least one ~~or more~~ fillers ~~filler~~; and

(c) at least one ~~or more~~ wetting agents ~~agent~~ and or surfactants ~~surfactant~~.

33. **(Currently amended)** A botanical drug or dietary supplement as claimed in ~~claims claim~~ 32 wherein the xanthan gum has a molecular weight of from 3.5×10^6 to 4.0×10^6 .

34. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 32 wherein the wetting agent is a polyethylene glycol or macrogol.

35. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 further ~~comprising~~ including one or more of a disintegrating agent, a lubricant, a sweetening agent, a flavouring agent and a viscosifying agent.

36. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 ~~which is~~ wherein the extracts are packaged in a sachet.

37. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 30 which is packaged with a dispensing container.

38. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim 37 wherein the dispensing container has a sealable lid.

39. **(Currently amended)** A botanical drug or dietary supplement as claimed in claim [[9]] 1 comprising wherein said extracts are botanical drug substances in [[a]] the following unit dose doses:

- (i) 0.200g to 0.250g of a botanical drug substance from [[a]] *Silybum spp.*;
- (ii) 0.585g to 1.95g of a botanical drug substance from [[a]] *Astragalus spp.*;
- (iii) 0.225g to 0.375g of a botanical drug substance from [[a]] *Salvia spp.*; and
- (iv) 0.150g to 0.600g of a botanical drug substance from [[a]] *Schisandra spp.*.

40. **(Currently amended)** A method of treating a patient to reduce or alleviate the symptoms of Hepatitis, particularly Hepatitis C, or to support healthy liver function comprising administering to a patient an efficacious dosage of [[a]] the botanical drug or dietary supplement as claimed in claim 1.

41. **(Currently amended)** The use of a botanical drug or dietary supplement to reduce or alleviate the symptoms of Hepatitis, particularly Hepatitis C, or to support healthy liver function, comprising administering to a patient an efficacious dosage of the botanical drug or dietary supplement as claimed in claim 1 in combination with another drug, said another drug being present in an amount efficacious to reduce or alleviate the symptoms of Hepatitis, particularly Hepatitis C, or to support healthy liver function.

42. **(Currently amended)** The use as claimed in claim 41 wherein the another drug is interferon.

43. **(Cancelled)**

44. **(Cancelled)**

45. **(Cancelled)**

46. **(Cancelled)**

47. **(Cancelled)**

48. **(Cancelled)**

49. **(Cancelled)**